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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,326	07/26/2000	William G. Hubbard	047542/0197	8619

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,326

Applicant(s)

HUBBARD ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004 and 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 57-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 16-18, 30, 31 and 36-38 is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15, 19-27, 32-35, 39-41 and 57-64 is/are rejected.
- 7) ☒ Claim(s) 11, 23-26, 28, 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed May 10, 2004 and supplemental response filed June 7, 2004. Claims 1-41 and 57-64 were pending. Applicants amended claims 1, 10, 16, 30 and 36. Claims 1-41 and 57-64 are pending and will be examined.
2. Applicants' amendments overcame the following: objection to claims 10, 11, 16-18, 30, 31 and 36-38; rejection of claims 1-5, 7, 8, 19-28, 39, 40, 41 and 57-64 under 35 U.S.C. 102(b) as anticipated by Hisatsuka et al.; rejection of claims 1-7, 12, 13, 19-28, 32, 33, 39, 40, 41 and 57-64 under 35 U.S.C. 102(e) as anticipated by Ammann et al.; rejection of claims 1, 2, 9, 21, 22 and 29 under 35 U.S.C. 102(b) as anticipated by Chibata et al. All other rejections are maintained for reasons given in the "Response to Arguments" section below.

Response to Arguments

3. Regarding previously presented art rejections and interpretation of claim terms, Applicants present two main arguments:

A) The limitation of the polysaccharide gel maintaining the biomaterial homogeneously suspended in the tissue augmentation material is not an intended use limitation. Applicants assert that Staley et al. do not teach a biomaterial homogeneously suspended in a carrier both before and during the introduction of the tissue augmentation material into a tissue site.

B) With regard to the term "rounded and substantially spherical", Applicants argue that the definition of this term is provided in the specification, and that not all of the particles fit this definition. Applicants provided a copy of the interference case decision from the Board of Appeals which supports Applicants position.

Regarding A), the limitation of the biomaterial being homogeneously suspended in a carrier is given weight, but not the limitation of the homogeneity being maintained before and during the

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introduction of the tissue augmentation material into a tissue site. The latter limitation simply describes a temporal effect, which does not place a structural constraint on the tissue augmentation material. Staley et al. teach a suspension of ceramic or metal particles in a polymer (polysaccharide) solution, in which the particles form substantially non-agglomerated suspension (Abstract; col. 3, lines 1-9; col. 8, lines 39-50). Therefore, since Applicants did not define the term "homogeneously suspended" in the application, a substantially non-agglomerated particle suspension is equivalent to a homogeneously suspended solution.

Regarding B), Applicants' definition is (page 10, lines 18-28):

"The term "substantially spherical" refers to the fact that while some of the present particles may be spheres, most of the particles of the present invention are sphere-like in their shape, i.e., they are spheroidal. FIGURE 1 is illustrative of these spheroidal or substantially spherical characteristics. The terms rounded" or "smooth, rounded" as used herein refers to the fact even though the present particles are not perfect spheres, they do not have any sharp or angular edges."

Staley et al. teach metal and ceramic particles with diameters of less than 50 microns (col. 4, lines 64-66, for example). Since only one dimension is given, this means that the particles are spherical, and, therefore, inherently meet the definition of "substantially spherical" provided by Applicants. In terms of the "smooth and rounded" terms, Staley et al. teach metal and ceramic (alumina) particles, which inherently possess the claimed characteristics.

Therefore Staley et al. teach the claim limitations which Applicants consider as critical to their invention.

Claim Objections

4. Applicant is advised that should claims 3-6 be found allowable, claims 23-26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Both sets of claims depend from claim 1 and have exactly the same limitations. It seems that claims 23-26 were intended to be dependent from claim 21.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-9, 11, 12-15, 19, 20, 23-26 and 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2-9, 12-15, 19, 20, 23-26 and 57-60 recite the limitation "the carrier" in line 1. There is insufficient antecedent basis for this limitation in the claims. Claims 2-9, 12-15, 19, 20, 23-26 and 57-60 are dependent from claim 1, which was amended to recite a tissue augmentation material.

B) Claim 11 recites the limitation "the carrier" in line 1. There is insufficient antecedent basis for this limitation in the claims. Claim 11 is dependent from claim 10, which was amended to recite a tissue augmentation material.

Claim interpretation

7. For the purpose of art rejections, the limitation of the polysaccharide gel viscosity in claims 1, 21 and 41 is interpreted in the following way:

A) for carboxymethylcellulose gels, examples of which are provided by Applicants on pages 27, 36, 38, 43-49, any carboxymethylcellulose gel with weight % concentration between 0.25 and 5% will be considered as possessing viscosity in the range of 20,000 to 350,000 centipoise;

B) for all the other polysaccharides, for which examples of concentration ranges and viscosities have not been provided, any concentration of the polysaccharide will be considered as fulfilling the viscosity requirement.

Properties of the polysaccharide gel such as “biocompatible”, “resorbable” and “lubricous” are inherent properties of the polysaccharide gels, therefore a prior art disclosing polysaccharide gels anticipates a claim to such gels being biocompatible, resorbable and lubricous. In addition, properties of ceramic particles such as “biocompatible”, “non-resorbable” and “finely divided” are inherent properties of spherical ceramic particles, therefore a prior art disclosing spherical ceramic particles anticipates a claim to such particles being biocompatible, non-resorbable and finely divided (see MPEP 2112.01).

2112.01 Composition, Product, and Apparatus Claims

PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”

In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated “such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate.” The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); Northam Warren Corp. v. D. F. Newfield Co., 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

8. Limitations of claims 1, 21 and 41 pertaining to maintaining the homogeneous suspension of biomaterial before and during the introduction of the tissue augmentation material into a tissue site (emphasis added) are not given weight, since they simply describe a temporal effect, which does not place a structural constraint on the tissue augmentation material.

9. Limitations of claims 19, 20, 39 and 40 are intended use limitations, which do not provide any structural constraints on the product of claims 1 and 21 in terms of comparison of the product with compositions described in the prior art.

10. The term "biomaterial" has not been defined, therefore it will be interpreted as any material. Applicants argued that the meaning of the term "biomaterial" should be a material which is compatible with a living tissue. However, Applicants did not define this term in the specification.

11. Applicants' definition of the terms "substantially spherical" and "rounded" is (page 10, lines 18-28):

"The term "substantially spherical" refers to the fact that while some of the present particles may be spheres, most of the particles of the present invention are sphere-like in their shape, i.e., they are spheroidal. FIGURE 1 is illustrative of these spheroidal or substantially spherical characteristics. The terms rounded" or "smooth, rounded" as used herein refers to the fact even though the present particles are not perfect spheres, they do not have any sharp or angular edges."

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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13. Claims 1-3, 7, 12-15, 19-23, 27, 32-35, 39-41 and 57-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Staley et al. (U.S. Patent 5,503,771).

Regarding claims 1, 19, 20, 21, 39, 40 and 41, Staley et al. teach suspensions of colloidal particles (= biomaterial) in polysaccharide gels, such as alginate, agar or agarose (col. 4, lines 20-31 and 39-50; col. 6, lines 1-6 and 61-67; col. 7, lines 1-10; col. 12, lines 50-65; col. 13, lines 46-48 and 59-67). The particles form a substantially non-agglomerated suspension (Abstract; col. 3, lines 1-9; col. 4, lines 26-28; col. 8, lines 39-50). Therefore, even though Staley et al. do not specifically teach gel viscosities in the range of 20,000 to 350,000 centipoise, since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 20,000 to 350,000 cp, the gels of Staley et al. anticipate these claims. Further, since Applicants did not define the term "homogeneously suspended" in the application, a substantially non-agglomerated particle suspension is equivalent to a homogeneously suspended solution.

Regarding claims 2 and 22, Staley et al. teach aqueous polysaccharide gel (col. 4, lines 20-25; col. 6, lines 1-6).

Regarding claims 3 and 23, Staley et al. teach alginate, agar and agarose (col. 6, line 67; col. 7, lines 1-10; col. 13, lines 59-64).

Regarding claims 7 and 27, Staley et al. teach water solvent (col. 4, lines 20-25; col. 6, lines 1-6).

Regarding claims 12 and 32, Staley et al. teach biomaterials comprising colloidal metal or ceramic particles (col. 4, lines 20-23).

Regarding claims 13 and 33, Staley et al. teach biomaterials comprising ceramic particles (col. 4, lines 20-23).

Regarding claims 14 and 34, Staley et al. teach biomaterials comprising ceramic particles (col. 4, lines 20-23). The particles have a size less than 50 microns (col. 4, lines 64-67). Therefore, since only a single dimension is provided for these particles, this means that the particles are spherical, and, therefore, inherently meet the definition of “substantially spherical” provided by Applicants. In terms of the “smooth and rounded” terms, Staley et al. teach metal and ceramic (alumina) particles, which inherently possess the claimed characteristics. The other characteristics of the particles are inherent, as explained in the Claim Interpretation section.

Regarding claims 15 and 35, Staley et al. teach ceramics such as alumina (col. 4, lines 57-59).

Regarding claims 57 and 61, Staley et al. teach additives (col. 6, lines 44-56).

Regarding claims 58 and 62, Staley et al. teach a pH buffer (col. 6, lines 44-56).

Regarding claims 59, 60, 63 and 64, Staley et al. do not specifically teach gel viscosities in the range of 20,000 to 350,000 centipoise, but since Applicants did not provide guidance regarding concentrations of all possible polysaccharides which would result in viscosities in the range of 20,000 to 350,000 cp, the gels of Staley et al. anticipate these claims.

Allowable Subject Matter

14. Claims 10, 16-18, 30, 31 and 36-38 are allowed.

15. Claim 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. Claims 4-6, 8 and 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

17. Claims 24-26, 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS

August 11, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER
